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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,024	01/18/2002	Y. Tom Tang	PF-0724 USN	1370

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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Offic Action Summary	Application No.	Applicant(s)	
	10/048,024	TANG ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

1. Claims 1-66 are pending.

Improper Markush

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04.

"Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

The claims are improperly set forth as the genus claims encompassing multiple distinct and peptides, as identified and claimed, which fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 9, 11-12,16-18, 30-33 and 59-66 in part, drawn to the first elected special technical feature peptide, first method of making using nucleic acids, vector and host cell and first method of using in a method of treating disease

Group II, claim(s) 8 in part drawn to the second elected technical feature transgenic organism.

Group III, claim(s) 10, 34-36, 40-42, and 46-47 in part, drawn to the third elected technical feature antibody, method of using in a diagnostic test and method of making a polyclonal.

Group IV, claim(s) 13-14 in part, drawn to the second method of using the first elected technical feature polynucleotide in a hybridization assay.

Group V, claim(s) 15 in part, drawn to the third method of using the first elected technical feature polynucleotide in an amplification assay.

Group VI, claim(s) 19-20 in part, drawn to the fourth elected special technical feature agonist and method of using in a screening assay.

Group VII, claim(s) 21 in part, drawn to the second method of using the fourth technical feature agonist in a method of treating.

Group VIII, claim(s) 22-23 in part, drawn to the fifth special technical feature antagonist and method of using in a screening assay.

Group IX, claim(s) 24 in part, drawn to the second method of using the fifth technical feature antagonist in a method of treating.

Group X, claim(s) 25 in part, drawn to the fourth method of using the first elected technical feature polypeptide in a binding assay.

Group XI, claim(s) 26 in part, drawn to the fifth method of using the first elected technical feature polypeptide in an assay for modulating activity.

Group XII, claim(s) 27 in part, drawn to the sixth method of using the first elected technical feature polynucleotide in an assay for altering expression.

Group XIII, claim(s) 28 in part, drawn to the seventh method of using the first elected technical feature polypnucleotide in an assay for assessing toxicity.

Group XIV, claim(s) 29 in part, drawn to the eighth method of using the first elected technical feature polynucleotide in an assay for altering expression with a compound.

Group XV, claim(s) 37-39 in part, drawn to the second method of using the third elected technical feature antibody in an in vivo method of diagnosis.

Group XVI, claim(s) 43-45 in part, drawn to the second method of making the third elected technical feature antibody.

Group XVII, claim(s) 48 in part, drawn to the third method of using the third elected technical feature antibody in a method for detecting.

Group XVIII, claim(s) 49 in part, drawn to the fourth method of using the third elected technical feature antibody in a method for purifying.

Group XIX, claim(s) 50-58 in part, drawn to the sixth elected technical feature microarray or array and first method of using the microarray in a method for generating a transcript image.

4. Furthermore, in addition to the election of one of the above V groups, further restriction is required under PCT Rule 13.1 to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

If one of Groups I-IV above are elected then a single designated amino acid composition selected from SEQ ID NO's:1-4 is required to be designated to which the search will be limited.

If Group V above is elected then a single designated nucleic acid composition selected from SEQ ID NO's:5-8 is required to be designated to which the search will be limited.

5. The inventions listed as Groups I-XIX and the distinct nucleic and amino acids do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the peptides and nucleic acids differ in sequence structure, length, function, effects and capable use. The methods use different steps and different reagents corresponding to the distinct special technical features, and exhibit different effects, functions and outcomes.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-XIX and a single molecular embodiment (sequence) as set forth above to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-XIX nor the single

molecular embodiment (sequence) are species election requirements; rather each of I-XIX and the elected sequence are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C.

101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
November 13, 2003